November 5, 2015

Karen B. DeSalvo, M.D., M.P.H., M.Sc.
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Ave, SW
Washington, DC 20001

Dear Dr. DeSalvo:

I am pleased to submit our comments on behalf of Allscripts to the Office of the National Coordinator for Health IT (ONC) on the Draft 2016 Interoperability Standards Advisory (ISA). Allscripts, with a platform of clinical and business solutions for ambulatory, acute and post-acute care settings, is relied upon by the largest network of providers – almost 180,000 physicians in almost 50,000 different practice locations, 1,500 hospitals and almost ten thousand extended care facilities. It is through our three decades of experience developing and deploying software to this vast network of providers that we are able to submit informed comments today.

In addition to our contributions to the comments submitted by the Electronic Health Records Association, we offer the following suggestions and responses to ONC's suggestions within the ISA.

Section I: Best Available Vocabulary/Code Set/Terminology Standards and Implementation Specifications

I-A: Allergies

Interoperability Need: Representing patient allergic reactions

These four rows for Allergy do not reflect the published set and priority order from C-CDA R2.1, where it states: ...the available code systems in the following priority order: NDFRT, then RXNORM, then UNII, then SNOMED CT. Additionally, specification of an entire standard vocabulary, like SNOMED-CT, is not useful; these should be represented as a value set.

Interoperability Need: Representing patient allergens: medications

Reporting at the correct level is important, and often applications use codes that are too specific. Allergy to Medication Class should be a separate row, with NDF-RT as mentioned in the note. Documenting the standard to report allergic to penicillins is important.

Interoperability Need: Representing patient allergens: food substances

This row for Allergy does not reflect the published set and priority order from C-CDA R2.1, where it states: ...the available code systems in the following priority order: NDFRT, then RXNORM, then UNII, then SNOMED CT. Additionally, specification of an entire standard vocabulary, like SNOMED-CT, is not useful; these should be represented as a value set.

Interoperability Need: Representing patient allergens: environmental substances

This row for Allergy does not reflect the published set and priority order from C-CDA R2.1, where it states: ...the available code systems in the following priority order: NDFRT, then RXNORM, then UNII, then SNOMED CT. Additionally, specification of an entire standard vocabulary, like SNOMED-CT, is not useful; these should be represented as a value set.

I-C: Encounter Diagnosis

Interoperability Need: Documenting patient encounter diagnosis

Please do not list two different Standards - that only leads to confusion and inconsistencies. Note also that, again, consistency with C-CDA R2.1 is useful, which suggests to drop the ICD-10-CM row and only use SNOMED-CT.

I-G: Gender Identity, Sex, and Sexual Orientation

Interoperability Need: Representing patient gender identity

Suggesting use of SNOMED-CT is not useful; this should be represented as a value set.

Interoperability Need: Representing patient sex (at birth)

This assumes use of CDA, or some HL7 RIM based reporting, and such a restriction limits the use of this recommendation. Better approach would be to extend the value set used for HL7 Administrative Gender.

Interoperability Need: Representing patient sexual orientation

Suggesting use of SNOMED-CT is not useful; this should be represented as a value set.

I-H: Immunizations

Interoperability Need: Representing immunizations – historical

Drop this from the list. MVX cannot be used on its own.

Interoperability Need: Representing immunizations – administered

Again, listing two standards is not helpful. Remove this.

I-J: Lab tests

Interoperability Need: Representing laboratory tests and observations

Strike the second bullet about those not using LOINC.

I-O: Procedures

Interoperability Need: Representing medical procedures performed

Again, multiple standards listed are not helpful. These may indeed represent different concepts, in which case we should have 3 rows, but otherwise drop the next two rows.

I-Q: Smoking Status

Interoperability Need: Representing patient smoking status

Should be represented as a value set.

I-R: Unique Device Identification

Interoperability Need: Representing unique implantable device identifiers

There is still an incredible amount of industry and technical churn over what exactly needs to be represented from the UDI. Even FDA recent recommendations were not well understood at the recent HL7 working group meeting.

Section II: Best Available Content/Structure Standards and Implementation Specifications

II-B: Care Plan

Interoperability Need: Documenting patient care plans

Support for care plans and the more general care planning by snapshot documents is not sustainable nor efficient. New work needs to be brought forward to establish methods for dynamic care planning.

Additionally - the Care Plan document type in C-CDA R2.1 is new and there is no track record to suggest that this is going to prove useful.

II-C: Clinical Decision Support

Interoperability Need: Shareable clinical decision support

Limitations on consumption of knowledge artifacts based on external HeD content partners. Large work effort seen by Common CDS to advance technology to consume knowledge artifacts and share these with the EHRs. The work required by the EHRs to shift from building order sets and documentation templates to consuming standardized documentation templates and order sets through CDS will be large. Need to better understand the clinical workflows and limitations on the EHR side in relation to consumption of HeD documentation templates and order sets. Questions concerning where CDS can consume the knowledge artifacts from, how CDS will manage the content (author) and how CDS will deliver the content once consumed to the EHRs are still outstanding.

II-D: Drug Formulary & Benefits

Interoperability Need: The ability for pharmacy benefit payers to communicate formulary and benefit information to prescribers systems

Compliance date for Formulary 3.0 was July 2014. We are supportive of the concept of RTPBI, however there are some challenges with RTPBI implementation as it relates to prescriber workflow that need to be addressed if RTPBI is going to be used as a replacement for formulary and benefit information. Also, the NCPDP Telecom D.0 standard could be modified and used as an alternative to RTPBI.

II-E: Electronic Prescribing

Interoperability Need: Cancellation of a prescription

In Surescripts Routing Enhancement MRD.

Interoperability Need: Pharmacy notifies prescriber of prescription fill status

There is interest in the prescriber community for this transaction. Pharmacies have not yet begun to adopt Fill Status.

Interoperability Need: A prescriber's ability to obtain a patient's medication history

Medication history is more commonly available from the pharmacy benefit managers than the pharmacies themselves. Analysis is needed on the completeness and timeless of currently available medication history.

II-F: Family health history (clinical genomics)

Interoperability Need: Representing family health history for clinical genomics

Implementation effort is grossly underestimated.

II-I: Patient Education Materials

Interoperability Need: A standard mechanism for clinical information systems to request context-specific clinical knowledge form online resources

Already supported in Meaningful Use Stage 2: Common CDS is currently in full support of this document.

II-J: Patient Preference/Consent

Interoperability Need: Recording patient preferences for electronic consent to access and/or share their health information with other care providers

Should clarify that BPPC, and XUA work in conjunction with the XD family of profiles.*

Additionally, XUA is not really relevant here for consent as it is used for to convey user authentication information across enterprises.

II-M: Representing clinical health information as a "resource"

Interoperability Need: Representing clinical health information as "resource"

This row, representing clinical health information as a "resource" looks out of place as this is not an interoperability concept per se.

II-N: Segmentation of sensitive information

Interoperability Need: Document-level segmentation of sensitive information

DS4P is an overly ambitious, un-implemented, untested implementation guide.

Section III: Best Available Standards and Implementation Specifications for Services

III-A: An unsolicited "push" of clinical health information to a known destination

Interoperability Need: An unsolicited "push" of clinical health information to a known destination between individuals

When there are multiple implementation specifications, the relationship and dependencies between these implementation specifications and standards should be explicit.

FHIR is very confusing; is it intended as a transport or payload? FHIR should be associated to MHD (references FHIR Document Resource with any payload).

It is not clear, if those are performed by the standard and implementation specifications, or are gaps that need to be addressed.

Interoperability Need: An unsolicited "push" of clinical health information to a known destination between systems

SOAP-Based Secure Transport Requirements Traceability Matrix (RTM) version 1.0 specification

The caveats being the application of the NHIN Authorization Framework to generate the needed SAML token and the use of UDDI for service discovery. This is less a standard itself and more an amalgam of other standards which for the most part look to be complaint with IHE XDS.b with the NHIN Authorization Framework applied.

Given that we are pushing standards based documents to known systems the use of UDDI is uncalled for as it is intended to solve the problem of service discovery and change. Moreover, just looking around it would seem that UDDI support has been dropped from windows as of Window Server 2012. So I think that this requirement has aged past its usefulness.

IHE-XDR (Cross-Enterprise Document Reliable Interchange)

This is a well-known stable standard that is broadly supported.

NwHIN Specification: Authorization Framework

The standard does not make sense as written. It has gone through 3 major revisions, all of which result in the generation of a header which violates WS-Security as per Microsoft.

NwHIN Specification: Messaging Platform

The example in this document did not use a SAML token but did correctly use a Binary Security Token instead of transmitting the token in plaintext. This is the crux of our complaint with the NHIN Authorization Framework, in that singing the WS-Security header mandates that it be encrypted as well.

IHE-XDR (Cross-Enterprise Document Reliable Interchange)

III-B: Clinical Decision Support Services

Interoperability Need: Providing patient-specific assessments and recommendations based on patient data for clinical decision support

Limitations on consumption of ECA rules, order sets and documentation templates based on external HeD content partners. Large work effort seen by Common CDS to advance technology to consume knowledge artifacts and share these with the EHRs. The work required by the EHRs to shift from building order sets and documentation templates to consuming standardize documentation templates and order sets through CDS will be large. Need to better understand the clinical workflows and limitations on the EHR side in relation to consumption of HeD documentation templates and order sets. Questions on where we consume the knowledge artifacts from, how we manage the content (author) and delivery to the EHRs.

Thank you for the opportunity to provide input on the important topics enclosed. We welcome the chance to speak with anyone within the ONC organization, should you have any questions.

Leigh Burchell
Vice President, Policy & Government Affairs
Allscripts
(919) 247-1144
leigh.burchell@allscripts.com